



i-STAT 1 DOWNLOADER

Function

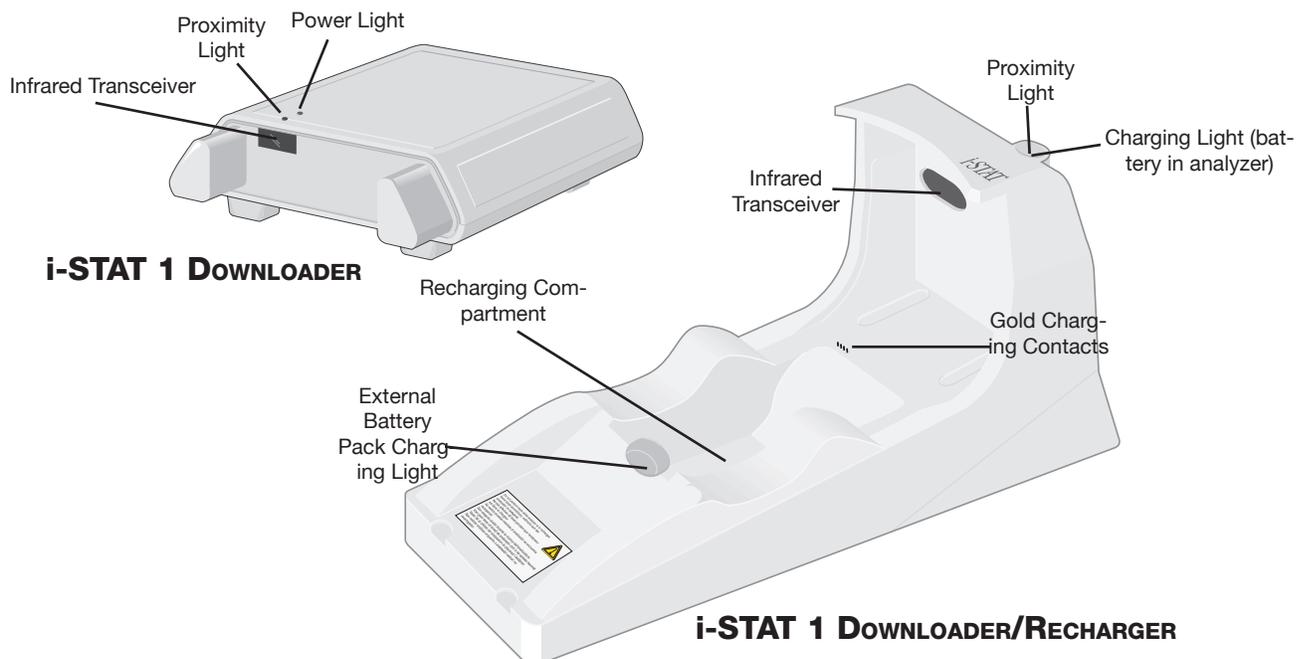
The Downloader converts infrared transmissions of test records from the analyzer to electrical form and transmits (uploads) them to the Data Manager. The Downloader also converts electrical signals from the Central Data Station to infrared transmissions, which are transmitted (downloaded) to the analyzer. Transmission is automatic when an analyzer is placed in a Downloader.

The Downloader comes in two formats:

- ✧ Downloader: A low-profile table-top unit with “arms” between which the analyzer is placed, and
- ✧ Downloader/Recharger (DR): a cradle that the analyzer is placed within.

Both Downloader formats are available for use with direct wiring (serial format) or ethernet cabling (network format). Unless indicated otherwise, references to the Downloader apply to the Downloader/Recharger as well.

The Downloader/Recharger can recharge a rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging automatically as soon as the analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.



Specifications

Specification	Downloader	Downloader/Recharger
Size	5.25in (13.3cm) Wide 6.75in (17.2cm) Long 2.13in (5.4cm) High	4.12in (10.4cm) Wide 10.25in (26.cm) Long 5.00in (12.7cm) High
Weight	0.6 lbs (0.27kg)	1.2 lbs (0.55kg)
Power	AC-DC power adapter or PC/Downloader adapter. Input 12V $\overline{\text{---}}$	AC-DC power adapter or PC/Downloader adapter.* Input 12V $\overline{\text{---}}$
Operating Temperature	0 to 40°C 32 to 104°F	0 to 40°C 32 to 104°F
Storage Temperature	-20 to 50°C -4 to 122°F	-20 to 50°C -4 to 122°F
Pollution Degree (Allowable ambient pollution level)	2	2
Installation Category (Allowable overvoltage specification)	2	2
Communication To Central Data Station and other equipment	Serial (RS232), or Ethernet	Serial (RS232), or Ethernet
Communication Link To and From Analyzer	Infrared Transceiver	Infrared Transceiver
Indicator LEDs Power Proximity Charge	Green Red NA	NA Blue Red/Green
Configuration	By host computer	By host computer

Power Supply

Specification	Downloader and Downloader/Recharger
Input	100 - 240V~ 47 - 63 Hz .9 - .5A
Output	12V $\overline{\text{---}}$ 3A max

* Recharge feature cannot be used in this configuration.

Running Cartridges in an Analyzer Docked in a Downloader/ Recharger

All i-STAT cartridges may be run in Handhelds that are docked in a Downloader/Recharger.

**Downloader/
Recharger Indicator
LEDs**

Analyzer Battery LED (near top of Downloader/Recharger)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging
SPARE BATTERY (near middle of Downloader/Recharger)	
Off	No Rechargeable Battery
Green	Trickle Charging

Power Requirements

The Downloaders require one power outlet. The Downloader and Downloader/Recharger must be used with the AC power supply adapter supplied with them. The Downloaders are capable of supplying power to the portable printer which reduces the number of power outlets required in the downloading and printing area.

**DR Affect on Ambient
Operating Temperature
Range**

The operating temperature for an i-STAT 1 Analyzer is 16°C to 30°C. The DR and Rechargeable Battery may raise the temperature of the i-STAT 1 Analyzer 2°C-3°C relative to the ambient temperature if:

- The Analyzer is frequently lifted and replaced into the DR
- Multiple thermally controlled cartridges are run in the Analyzer while it is in the DR.

**Programming and
Connections**

Details for programming the Network Downloaders can be found in the Downloader Programming and Wiring section of this manual. Diagrams and instructions for connecting peripheral components to the Downloader can also be found in the Downloader Programming and Wiring section.

Cautions

The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).

Users should not connect the Downloader or the Downloader/Recharger to a medical electrical system.

Do not place metal objects on or near the exposed gold charging contacts.

Be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as the disconnect device for the Downloader and Downloader/Recharger and, therefore, the socket outlet must be installed (or located) near the Downloader or Downloader/Recharger and must be easily accessible.

Only i-STAT provided printers may be connected to the Downloader printer port.

An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

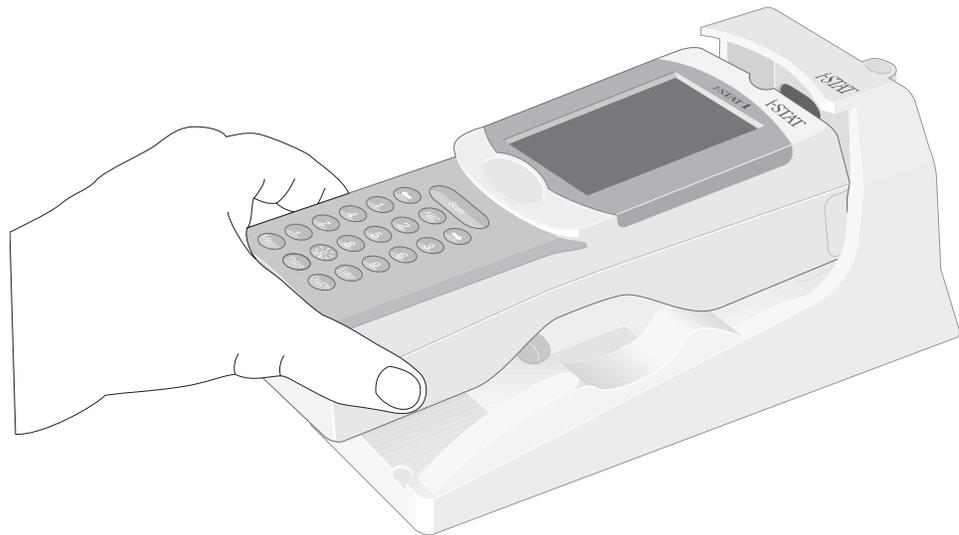


Transmitting Data from Downloader to the Data Manager

To transmit through a Downloader to the Data Manager, place the analyzer between the arms on the front of the Downloader with the test strip port end touching the Downloader. When properly aligned the red proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message “Communication in Progress” is displayed on the screen.

Transmitting Data from Downloader / Recharger to the Data Manager

To transmit data through a Downloader/Recharger, place the analyzer in the Downloader/Recharger’s cradle. When properly aligned, the blue proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message “Communication in Progress” is displayed on the screen.



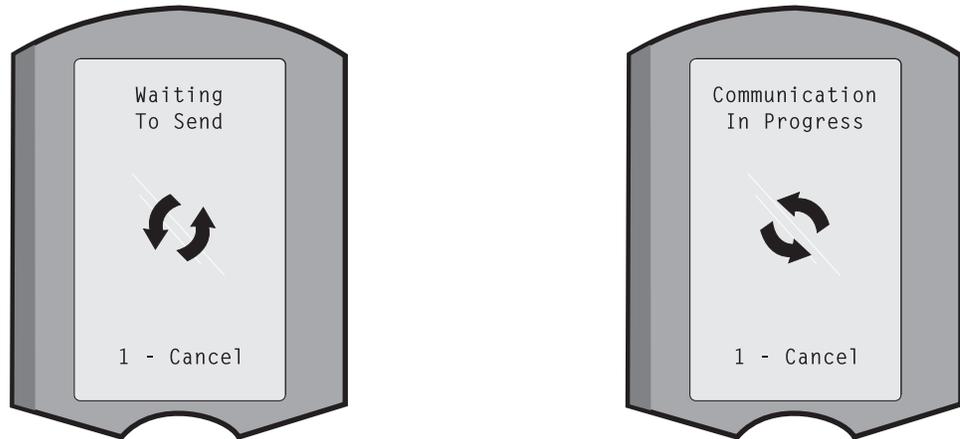
Transmitted Information

The following information is transmitted from the analyzer with each test record:

- ✧ The date and time the test was performed
- ✧ Operator ID and Patient ID or Quality Test fluid lot number
- ✧ All information entered by the operator, such as lot numbers, sample type and comment codes
- ✧ Result(s)
- ✧ Serial number of the analyzer
- ✧ Uses count of the analyzer
- ✧ Application software version in the analyzer
- ✧ Standardization software in the analyzer

Troubleshooting

The analyzer displays “Waiting to Send” until communication is established with the Central Data Station. When communication is established the message changes to “Communication in Progress” and the arrows circle until upload is complete. If the message does not change from “Waiting to Send” or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.



Charge Battery Before Use

Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/Recharger to download data until rechargeable battery is ready.

Keep Battery Charged

Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Charging the Rechargeable Battery

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

**Charging
Rechargeable Battery
in External Recharge
Compartment**

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

STEP	ACTION
1	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2	To remove the battery after it is charged, back the pack out of the compartment.

Full recharge from a discharged state takes approximately 40 hours

Caution

If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

PROGRAMMING THE NETWORK DOWNLOADERS

This section includes procedures to configure the network Downloaders to transmit data between the i-STAT 1 Analyzers and a data manager as well as from other peripheral devices to a computer running CDS.

Preparation

1. Determine for each Downloader: IP Address, Gateway Address, and Subnet Mask.
2. Determine the IP Address of the data manager and service port for i-STAT 1 Analyzer transmissions (default 6004).

Configure a Terminal Session

1. Run a terminal emulation program, such as HyperTerminal, and choose the following port settings:

Bits per second: **9600**

Data bits: **8**

Parity: **None**

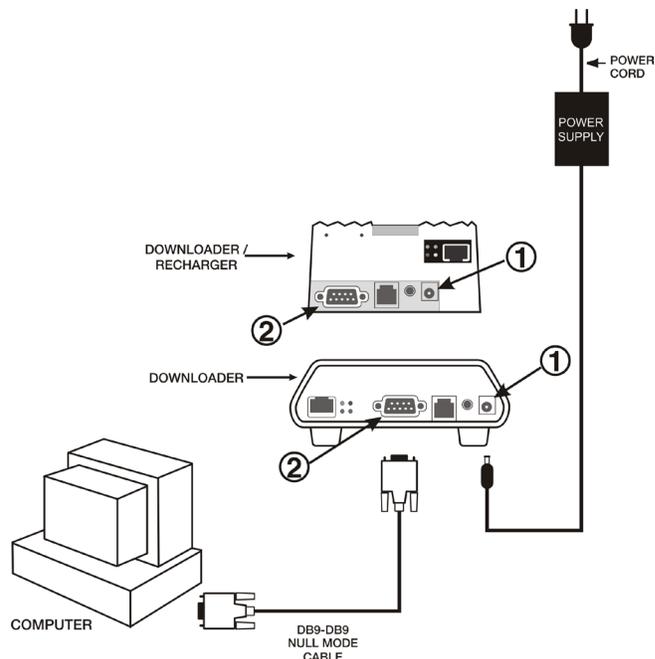
Stop Bits: **1**

Flow Control: **None**

Connect to and Program the Downloader

1. Connect one end of a Null-Modem Cable to the DB9 Port on the Downloader and connect the other end to the COM port selected in the Hyper Terminal session above to the computer with Hyper Terminal as shown below. **Do not apply power to the Downloader at this time.**

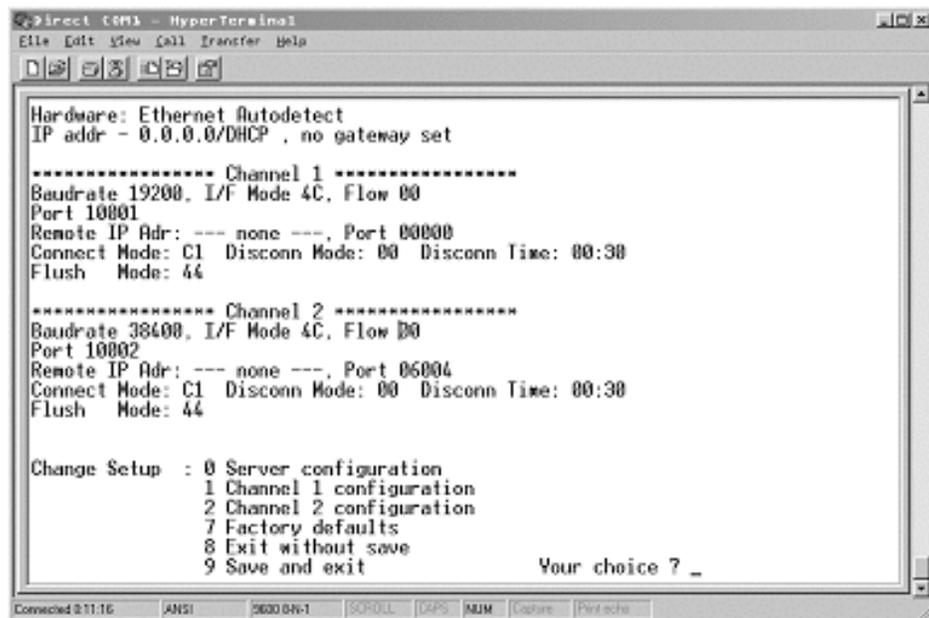
- ① Power In
- ② DB9



2. While holding down the **x** key on the PC keyboard, apply power to the Downloader. When the following screen is displayed release the **x** key:



3. Press the Enter key immediately to enter the Setup Mode:



Configure Server Parameters

Each network Downloader requires a static IP Address, a Gateway Address, and, if required, a Subnet Mask.

Note: Failure to assign a static IP address to the downloader could result in an i-STAT 1 Analyzer being programmed with an inappropriate customization profile.

The following describes how to configure the network Downloader's server parameters.

1. Determine the following site specific information for this Downloader:
 - IP Address (Example: 10.10.12.142 used below)
 - Gateway Address (Example: 10.10.12.1 used below)
 - Netmask (Example: 8 for 255.255.255.0 used below)
2. At the **Your choice?** prompt, Select **0** for Server Configuration and enter the information required for this Downloader.
3. At each of the prompts enter the bold-faced value.

Note: If the information to be entered is the same as the default value, press the Enter key.

 - IP Address: (000)**10**.(000) **10**.(000)**12**.(000)**142**
 - Set Gateway IP Address: (N) **Y**
 - Gateway IP addr: (000)**10**.(000)**10**.(000)**12**.(000) **1**
 - Netmask: Number of Bits for Host Part (00) **8**

Note: The Netmask is configured as the number of host bits required based on the subnet being used.

 - Change telnet config password: (N) **N**

Default Netmasks for Standard IP Networks

SUBNET MASK	HOST BITS	NETWORK TYPE
255.0.0.0	24	Class A
255.255.0.0	16	Class B
255.255.255.0	8	Class C

Netmasks for Other Networks

SUBNET MASK	HOST BITS	SUBNET MASK	HOST BITS
255.255.255.252	2	255.255.192.0	14
255.255.255.248	3	255.255.128.0	15
255.255.255.240	4	255.255.0.0	16
255.255.255.224	5	255.254.0.0	17
255.255.255.192	6	255.252.0.0	18
255.255.255.128	7	255.248.0.0	19
255.255.255.0	8	255.240.0.0	20
255.255.254.0	9	255.224.0.0	21
255.255.252.0	10	255.192.0.0	22
255.255.248.0	11	255.128.0.0	23
255.255.240.0	12	255.0.0.0	24
255.255.224.0	13		

Configure for i-STAT 1 Data Transfer via IR Port

Channel 2 provides network access for the i-STAT 1 Analyzer data transmissions to a data manager. This section describes how to set up parameters for Channel 2.

1. Determine the following information:
 - The IP Address of the data manager. (Example: 10.10.12.184)
 - The service port number set to receive transmissions from the i-STAT 1 Analyzer (default 6004).
2. At the **Your choice ?** prompt, Select **2** (Channel 2 Configuration).
3. At each of the prompts enter the following bold-faced value:

Note: If the information to be entered is the same as the default value, press the Enter key.

- Baudrate (38400) ? **38400** (*must be set to 38400*)
- I/F Mode (4C) ? (*press <Enter> key*)
- Flow (00) ? (*press <Enter> key*)
- Port No (10002) ? (*press <Enter> key*)
- ConnectMode (C1) ? **C1** (*must be set to C1*)
- Auto increment source port (N) ? **N** (*press <Enter> key*)
- Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**

Note: Set Remote IP Address to the IP Address of the computer where the data manager resides.

- Remote Port (06004) ? **6004**
Note: Remote Port refers to i-STAT 1 service port defined in the data manager.
- DisConnMode (00) ? (*press <Enter> key*)
- FlushMode (44) ? **44** (*must be set to "44"*)
- DisConnTime (00:30) ? **00:30** (*Disconnect time must be 30 seconds*)
- SendChar 1 (00) ? (*press <Enter> key*)
- SendChar 2 (00) ? (*press <Enter> key*)

Verify and Save Settings

1. When the Summary screen appears, verify that the information you entered is correct. If it is not, fix the appropriate settings and continue.

```
Direct COM3 - HyperTerminal
File Edit View Call Transfer Help
-----
Hardware: Ethernet Autodetect
IP addr 010.010.012.142, gateway 010.010.012.001
----- Channel 1 -----
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: 010.010.012.184, Port 00101
Connect Mode: C1 Disconn Mode: 00 Disconn Time: 00:30
Flush Mode: 44
----- Channel 2 -----
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: 010.010.012.184, Port 06004
Connect Mode: C1 Disconn Mode: 00 Disconn Time: 00:30
Flush Mode: 44
Change Setup : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit
                Your choice ? _
-----
Connected:013:43 ANS 9600 B4-1 [SCROLL] [SAFE] NUM [Capture] [Print] [Close]
```

2. Save the settings by selecting **9** (Save and Exit) at the **Your choice ?** prompt.
3. Remove power and connect the Downloader in its intended location.

Troubleshooting

If a wrong number is entered, which cannot be corrected, press the **Enter** key until the session is completed and start from the beginning again.

Configure for i-STAT 1 Serial Downloader Connection

Channel 1 provides network access for the i-STAT 1 Analyzer data transmissions to a data manager. This section describes how to set up parameters for Channel 1.

1. Determine the following information:
 - The IP Address of the data manager. (Example: 10.10.12.184)
 - The service port number set to receive transmissions from the i-STAT 1 Analyzer (default 6004).
2. At the **Your choice ?** prompt, Select **1** (Channel 1 Configuration).
3. At each of the prompts enter the following bold-faced value:

Note: If the information to be entered is the same as the default value, press the Enter key.

- Baudrate (38400) ? **38400 (must be set to 38400)**
- I/F Mode (4C) ? **(press <Enter> key)**
- Flow (00) ? **(press <Enter> key)**
- Port No (10001) ? **(press <Enter> key)**
- ConnectMode (C1) ? **C1 (must be set to C1)**
- Auto increment source port (N) ? **N (press <Enter> key)**
- Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**

Note: Set Remote IP Address to the IP Address of the computer where the data manager resides.

- Remote Port (06004) ? **6004**
- **Note:** Remote Port refers to i-STAT 1 service port defined in the data manager.
- DisConnMode (00) ? **(press <Enter> key)**
- FlushMode (44) ? **44 (must be set to "44")**
- DisConnTime (00:30) ? **00:30 (Disconnect time must be 30 seconds)**
- SendChar 1 (00) ? **(press <Enter> key)**
- SendChar 2 (00) ? **(press <Enter> key)**

WIRING THE DOWNLOADERS

Overview

This section includes diagrams to make a connection between the Downloaders and the Data Manager and to connect a printer to the Downloaders.

Caution

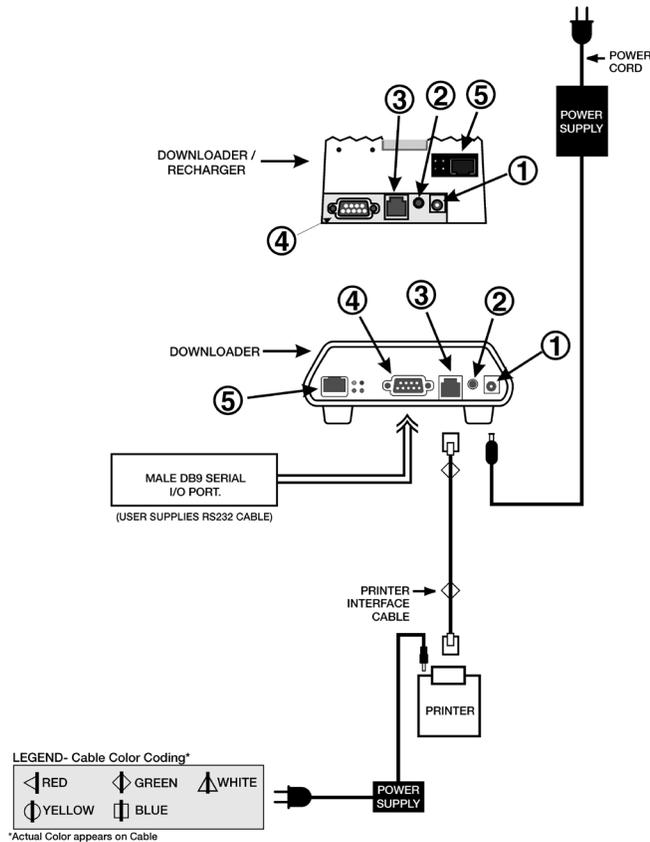
Only i-STAT provided printers may be connected to the Downloader printer port.

An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

Connecting the Network Downloader

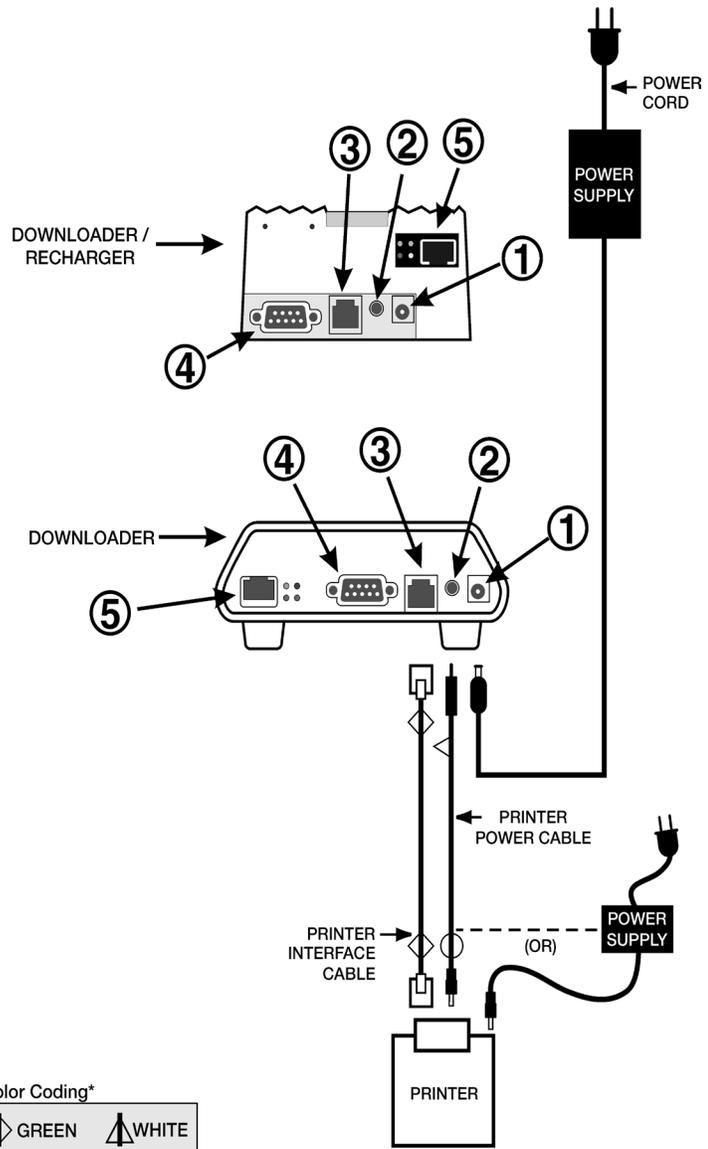
Option 1: The following diagram shows how to connect the portable printer to the network Downloader for communication. Parts required are:

- Printer Interface Cable
- Printer Power Adapter
- ① Power In
- ② Power Out
- ③ RJ11 (printer interface)
- ④ DB9
- ⑤ RJ45 (network)



Option 2: The following diagram shows how to connect the portable printer to the network Downloader for power and communication. Parts required are:

- Printer Interface Cable
 - Printer AC Adapter or Printer Power Cable
- ① Power In
 - ② Power Out
 - ③ RJ11 (printer interface)
 - ④ DB9
 - ⑤ RJ45 (network)



*Actual Color appears on Cable

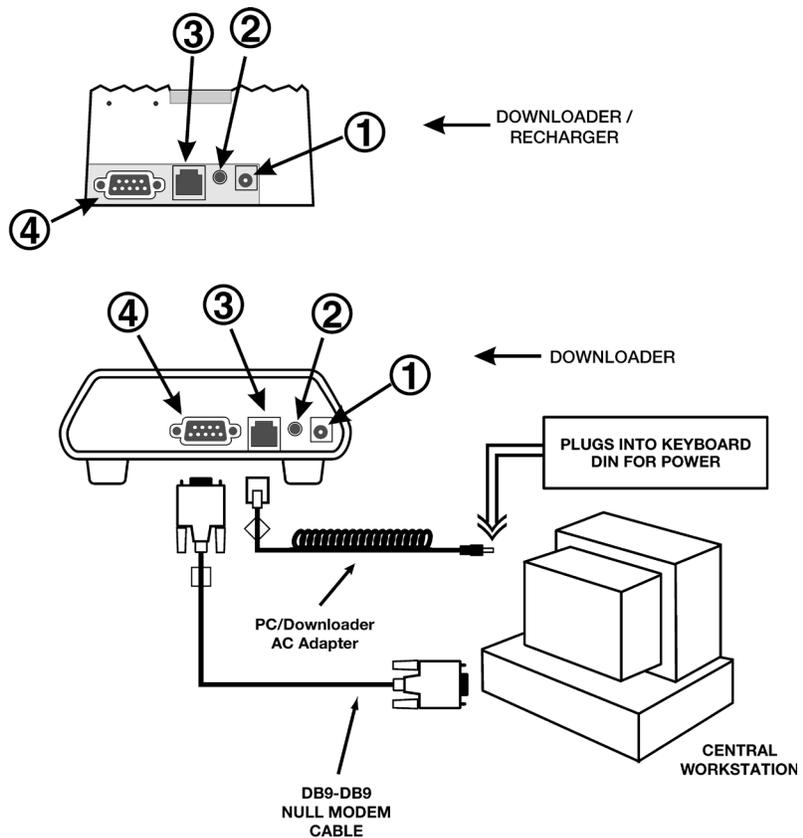
Connecting the Serial Port Downloader

Option 1: The following option is for downloading/uploading only and can be used when there is no power outlet available for the Downloader or Downloader/Recharger.

In this particular configuration, both recharging LED lights will be lit. The primary recharging LED will blink red and the alternate will be steady green. This is typical behavior, and does not indicate that any charging is taking place. In fact, batteries cannot be charged in the Downloader/Recharger in this configuration.

The following diagram shows how to connect a serial downloader locally to the Data Manager. Parts required are:

- PC/Downloader Adapter
- DB9-DB9 Null Modem Cable
- ① Power In
- ② Power Out
- ③ RJ11 (printer interface)
- ④ DB9



LEGEND- Cable Color Coding*

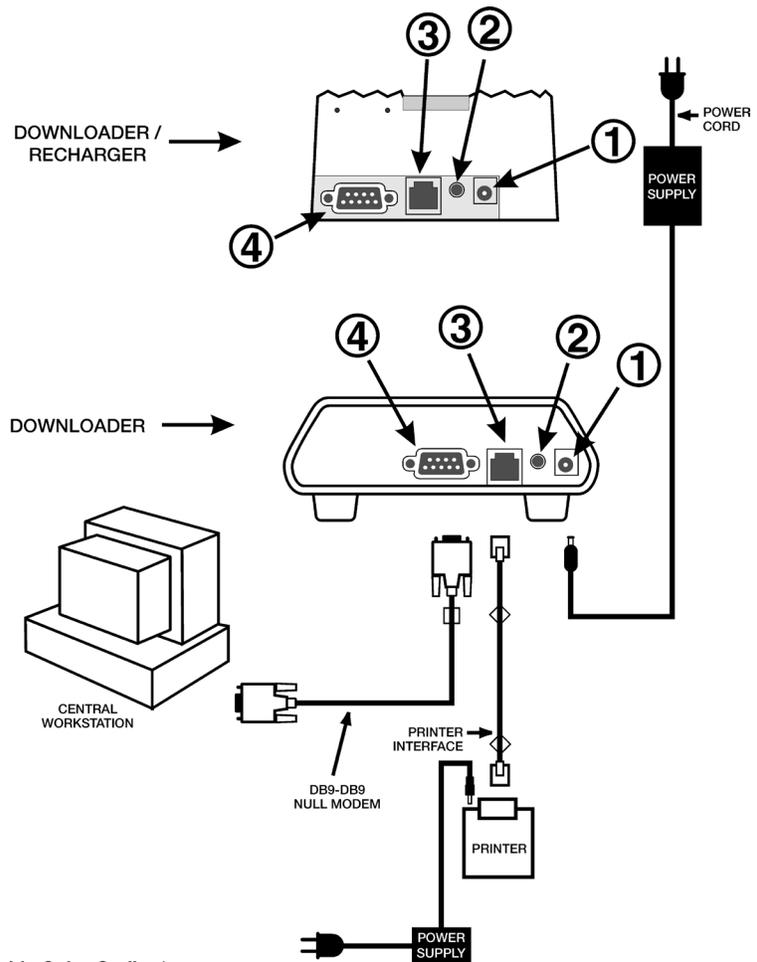
◁ RED	◇ GREEN	▲ WHITE
⊖ YELLOW	▢ BLUE	

*Actual Color appears on Cable

*CANNOT POWER PCx DOCKING STATION OR PRINTER IN THIS MODE

Option 2: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for communication. Parts required are:

- DB9-DB9 Null Modem Cable
 - Printer Interface Cable
 - Printer AC Adapter
- ① Power In
 - ② Power Out
 - ③ RJ11 (printer interface)
 - ④ DB9



LEGEND- Cable Color Coding*

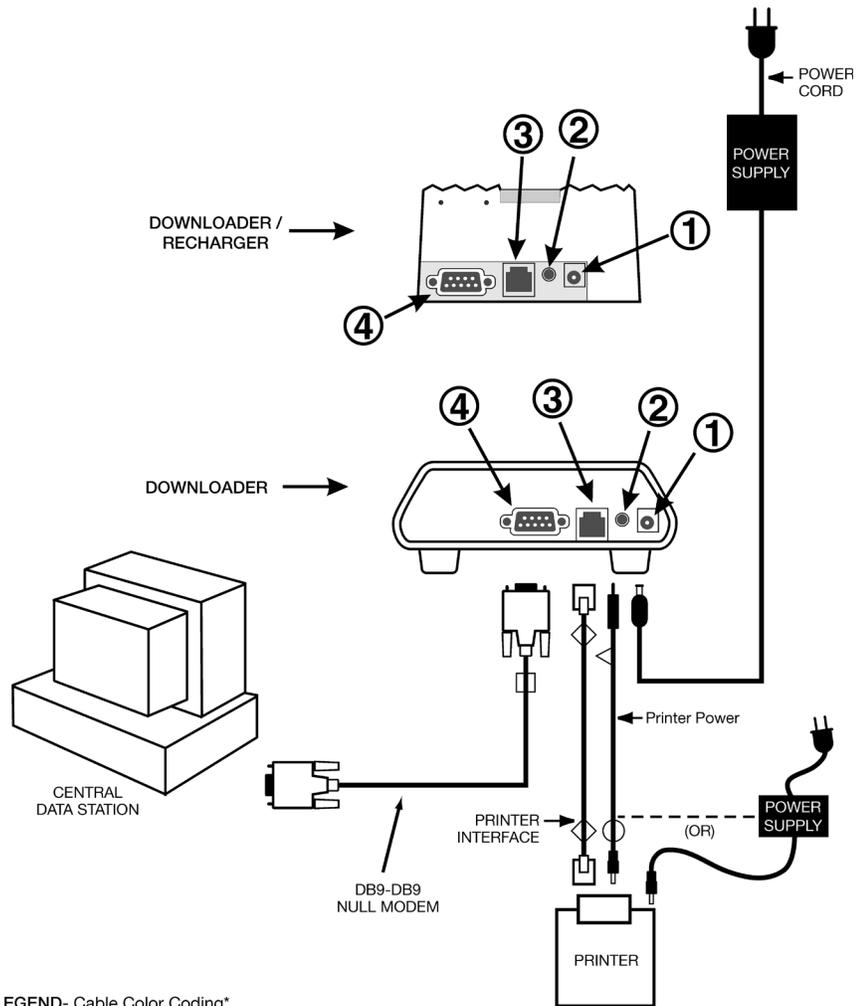
◀ RED	↔ GREEN	▲ WHITE
○ YELLOW	◻ BLUE	

*Actual Color appears on Cable

Option 3: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for power and communication. The printer can also be powered by its own AC adapter. Parts required are:

- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer Power Cable or Printer AC Adapter

- ① Power In
- ② Power Out
- ③ RJ11 (printer interface)
- ④ DB9



LEGEND- Cable Color Coding*

◁ RED	◇ GREEN	▲ WHITE
⊖ YELLOW	⊖ BLUE	

*Actual Color appears on Cable

i-STAT 1 DOWNLOADERS CAUTION STATEMENTS

Introduction

This Technical Bulletin provides guidance on Caution statements provided in the i-STAT 1 System Manual as to where i-STAT 1 Downloaders and Downloader/Rechargers may be placed and what may be connected to them.

The specific Caution statements being addressed are:

- a) The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient) and
- b) Users should not connect the Downloader or Downloader/Recharger to a medical electrical system.

The information in this Technical Bulletin supersedes the information provided for these two Caution statements in the following sections of the i-STAT System Manual:

- 1) Section 6 – i-STAT Downloader (Art:714368-01E, Rev. Date: 03/03/2008)
- 2) Section 21 – Downloader Programming and Wiring (Art: 714383-01E Rev. Date: 03/03/2008)

Note: In this document, the phrase “i-STAT 1 Downloaders” applies to the following: the i-STAT 1 Serial Downloader, the i-STAT 1 Serial Downloader/Recharger, the i-STAT 1 Network Downloader, and the i-STAT 1 Network Downloader/Recharger.

Location of i-STAT 1 Downloaders

The i-STAT 1 Downloaders should not be installed within 1.5 meters of a patient environment¹ as defined in International Electrotechnical Commission 60601-1². The i-STAT 1 Downloaders should not be installed in such a way that it is possible for a healthcare provider to make physical contact with both the i-STAT 1 Downloader and a patient simultaneously or in such a way that a patient may make physical contact directly with an i-STAT 1 Downloader while connected to a medical electrical system³ as defined in International Electrotechnical Commission 60601-1.

Connection of i-STAT 1 Downloaders

The i-STAT 1 Downloaders should not be connected to a medical electrical system.

The i-STAT 1 Downloader’s network connection and serial port should not be connected simultaneously, except under the following circumstances:

- An i-STAT 1 Serial Downloader or i-STAT 1 Serial Downloader/Recharger may be connected

to the serial port of an i-STAT 1 Network Downloader or an i-STAT 1 Network Downloader/Recharger.

- An Abbott Diabetes Care docking station used with the Precision PCx™ and/or Precision XceedPro™ hospital glucose instrument may be connected to the serial port of an i-STAT 1 Network Downloader or an i-STAT 1 Network Downloader/Recharger, provided the docking station is not connected to anything other than the i-STAT 1 Downloader.

¹ From IEC 60601:

PATIENT ENVIRONMENT: any volume in which intentional or unintentional contact can occur between a patient and parts of the ME EQUIPMENT or ME SYSTEM or between a patient and other persons touching parts of the ME EQUIPMENT or ME SYSTEM.

² Complete title: International Standard 60601 Third Edition 2005-12– Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.

³ MEDICAL ELECTRICAL SYSTEM (ME SYSTEM): combination, as specified by its manufacturer, of items of equipment, at least one of which is MEDICAL ELECTRICAL EQUIPMENT to be inter-connected by functional connection or by use of a power outlet.

MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT): electrical equipment having a part that is intended to come into physical contact with a patient.

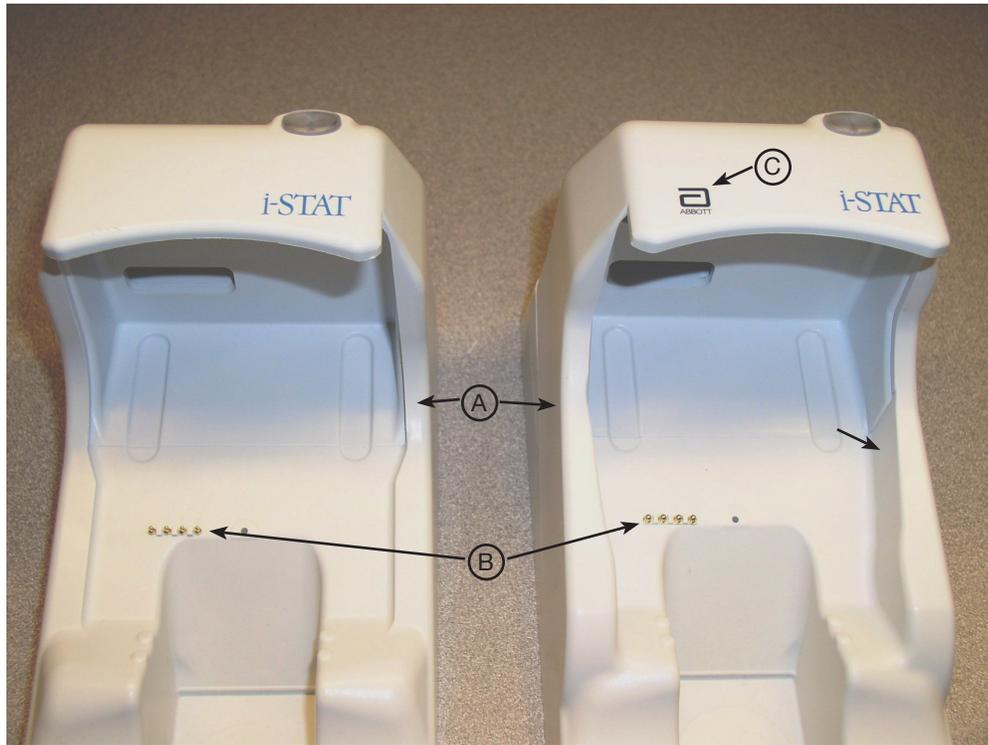
UPDATES TO THE I-STAT 1 DOWNLOADER/RECHARGERS

OVERVIEW

Abbott Point of Care continuously seeks to improve the reliability of our product lines. As such, we have made three (3) changes to our Downloader/Recharger products as described below.

Note: these changes do not impact the configuration or transmission instructions for the devices.

CHANGE DESCRIPTION



Current Downloader/Recharger

New Downloader/Recharger

- The side walls have been raised to prevent the insertion of a handheld at an angle or from the side. (A)
- The color of the recharge pins has been changed to silver, and their diameter has increased in size. (B)
- The front cover now has both the Abbott and i-STAT logos. (C)

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